December 17, 2004

ORGANIZATION: Nuclear Energy Institute (NEI)

SUBJECT: SUMMARY OF NOVEMBER 9, 2004, MEETING WITH NEI TO DISCUSS EMERGENCY PLANNING (EP) INSPECTIONS, TESTS, ANALYSES, AND ACCEPTANCE CRITERIA (EP ITAAC) AND DISCUSSION OF COMBINED LICENSE (COL) APPLICATION ISSUES

On November 9, 2004, a public meeting was held between the U.S. Nuclear Regulatory Commission (NRC) and NEI at NRC Headquarters in Rockville, MD. Staff from the Department of Homeland Security/Federal Emergency Management Agency (DHS/FEMA) also participated in the meeting. The purpose of this meeting was to discuss EP ITAAC and issues associated with a combined license (COL) application. A list of meeting attendees and the meeting agenda are included as Attachment 1.

NRC and NEI handouts were provided during the meeting. The handouts can be accessed through the Agencywide Documents Access and Management System (ADAMS) under Accession No. ML043240352 (Attachments 2 through 8). This system provides text and image files of NRC's public documents. If you do not have access to ADAMS or if there are problems in accessing the handouts located in ADAMS, contact the NRC Public Document Room (PDR) reference staff at 1-800-397-4209, 301-415-4737, or by e-mail to pdr@nrc.gov.

EP ITAAC Portion of the Meeting

The EP ITAAC portion of the meeting was a follow-up to NEI's letter dated September 15, 2004, (ADAMS Accession No. ML043230044), and a telephone conversation on November 2, 2004, between the NRC staff and NEI. The September 15, 2004, letter proposed various NEI revisions to the EP ITAAC based on discussions in previous meetings. During the November 2, 2004, telephone conversation the NRC staff discussed with NEI a revised EP ITAAC Table 13.3-1 (ADAMS Accession No. ML043200752), which reflected NEI's letter and the NRC staff's position on the proposed EP ITAAC.

During the meeting, the NRC staff and NEI agreed that the EP ITAAC reflected in Planning Standards 1.0 through 7.0 of Table 13.3-1 were acceptable. Therefore, the meeting was focused on resolution of outstanding issues associated with EP ITAAC in Planning Standards 8.0 and 9.0. During the meeting, NEI provided some minor editorial changes to Table 13.3-1.

The discussion of items 8.1.1 and 8.1.3, addressed the definition of onsite and offsite exercises, including when identified exercise deficiencies need to be corrected. An onsite deficiency, according to 8.1.1, would have to be corrected prior to fuel load. An offsite deficiency, according to 8.1.3, would be corrected prior to the reactor exceeding 5 percent of rated power. An ITAAC is based on events occurring prior to fuel load. Some aspects of EP, however, are based on events occurring prior to exceeding 5 percent of rated power. NEI pointed out that offsite deficiencies generally involve issues that are outside of the licensee's control. NEI also stated that the 120-day clock, for FEMA to verify corrections to deficiencies, might put a strain

on a new licensee. FEMA staff stated that current practices usually result in verifying deficiency corrections within the 120-day period.

The NRC staff quoted the regulation related to the issuance of a license, found in Title 10 of the *Code of Federal Regulations (*10 CFR) Section 50.47(d), which states that a license authorizing fuel loading and/or low power testing and training may be issued after the NRC finds that the state of onsite emergency preparedness provides reasonable assurance that adequate protective measures can and will be taken in the event of a radiological emergency.

The NRC staff suggested that if item 8.1.3 was not acceptable to the Commission, then a license condition could be written into a COL, which would state that the offsite deficiencies would be resolved prior to exceeding 5 percent of rated power. NEI questioned the NRC staff on the definition of a deficiency and a weakness, as they related to Item 8.1.1. The NRC staff stated that NRC Inspection Manual Chapter 0612, "Power Reactor Inspection Reports," provides a definition for these two terms.

For item 9.1, the NRC staff informed NEI that a licensee may need to submit an exemption request to the regulation (i.e., Appendix E to 10 CFR Part 50, Section V), to allow them to submit the procedures 180 days prior to fuel load, since the regulation states that the procedures are to be submitted 180 days prior to having "nuclear material" onsite. Both sides agreed that in the long term, the regulation needs to be changed. NEI questioned whether the letter that is submitted with the detailed implementing procedures could be used to verify that the ITAAC had been met. The NRC staff said it could be.

For item 8.1, the NRC staff commented that, in the column titled "Inspections, Tests, Analyses," the term "exercise" is not consistent with the term "test," used in the other items. It was agreed that the word "test" would appear in parenthesis after the words, "A full-participation exercise..." At the conclusion of the meeting, the NRC staff, FEMA, and industry had generally agreed on a final version of generic EP ITAAC, in support of COL applications and reviews.

Proposed Approach for Response to SRM-SECY-04-0032

The NRC staff presented a status of their approach to address SRM-SECY-04-0032, "Programmatic Information Needed for Approval of a Combined License Without Inspections, Tests, Analyses, and Acceptance Criteria." The staff noted that the following operational programs were listed in SECY-02-0067, "Inspections, Tests, Analyses, and Acceptance Criteria (ITAAC) for Operational Programs (Programmatic ITAAC)."

Emergency Planning	Physical Security
Quality Assurance	Fire Protection
Radiation Protection	Access Authorization
Fitness for Duty	Training
Licensed Operator	Reportability
Containment Leak Rate Testing	Maintenance Rule
Inservice Inspection and Inservice Testing	Equipment Qualification

The staff also noted that emergency planning would have ITAAC. In discussing ITAAC for the remaining operational programs listed above, staff requirements memorandum (SRM)-SECY-02-0067 stated the following:

> Although the NRC inspection process does not replace a particular ITAAC, an ITAAC should not be necessary if the program and its implementation are ***fully described*** in its application ***[emphasis added]***.

Additional clarification of the phrase "fully described" was provided in SRM-SECY-04-032:

> ... "fully described" should be understood to mean that the program is clearly and sufficiently described in terms of the scope and level of detail to allow a reasonable assurance finding of acceptability. Required programs should always be described at a functional level and at an increased level of detail where implementation choices could materially and negatively affect the program effectiveness and acceptability.

The staff stated that they plan to respond to SRM-SECY-04-0032 prior to December 31, 2005. The approach that has been proposed to address the SRM involves evaluating the information required by 10 CFR 52.79(b) to be submitted in the COL application (i.e., the final safety analysis report [FSAR]) plus any additional information necessary to fully describe the operational program, which would include a discussion of the program implementation. The staff would document their evaluation in the final safety evaluation report. For programs that were not implemented prior to the issuance of the COL, a condition would be placed in the license.

The staff noted that the Commission did not eliminate the possible utilization of ITAAC for operational programs. In fact, SRM-SECY-02-0067 states that the staff should inform the Commission if it plans to require any specific programmatic ITAAC for at least the first few COL applications. The staff stated that their proposed approach does not assume that all operational programs will have ITAAC. In addition, the staff stated that a COL applicant may propose ITAAC for selected operational programs for consideration by the staff.

NEI stated that they wanted to discuss which specific programs were part of this approach. One specific example cited by NEI was reportability, which NEI representatives did not believe was within the scope of this operational program discussion. The staff stated that reportability was one of the programs listed in SECY-02-0067. In addition, SRM-SECY-04-032 specified that the staff identify the information necessary in a COL application for nine specific operational programs (fire protection, training, quality assurance during operation, fitness for duty, access authorization, radiation protection, physical security, licensed operator, and reportability) and present those results to the Commission. The staff stated that they will likely perform this for all the operational programs listed in SECY-02-0067 with the exception of emergency planning. The staff and NEI both agreed to participate in public meetings starting early next year to discuss the information needed for specific operational programs beyond what will be included in the FSAR to support NRC staff review of that program.

Discussion of NEI's COL Application Guidance Document (NEI 04-01)

NEI presented the status of NEI 04-01. NEI stated that they plan to issue the draft COL application guide in December 2004 and would like the NRC staff to formally comment on the document. NEI stated that they are seeking endorsement of Revision 1 of the document by the end of 2005. NEI stated that this schedule supports the schedule of future COL applicants.

NEI provided a draft table of contents of the COL application guidance document which is included in Attachment 7 of this meeting summary. NEI stated that the guidance document is approximately 200 pages in length and contains two lengthy appendices. NEI stated that where they did not feel there was "controversy," specific guidance was included in the document. NEI did note that the status of the 10 CFR Part 52 rulemaking is complicating the development of the COL application guide.

The document includes chapter by chapter guidance for the FSAR, as well as COL action items (identified in the referenced design certification and early site permit [ESP] if applicable) as well as interface requirements. The document also identifies key references such as the NRC standard review plan (SRP), regulatory guides (RG), and unresolved safety issues/generic safety issues. Special topics that are discussed include the design reliability assurance program, ITAAC, plant-specific design ITAAC, and plant-specific technical specifications.

NEI also provided a revised figure outlining their proposed components of a COL application which is included as Attachment 6. The NRC staff previously reviewed this figure and provided comments in a public meeting dated January 29, 2004. NEI stated in this meeting that some of the comments have been incorporated into the figure but did not disposition each comment previously provided by the staff.

NEI stated that it was important to separate the design control document for a certified design from the site specific information contained in a COL application because there is a separate change process for each. The NRC staff stated that Section IV of each design certification rule in 10 CFR Part 52 contains requirements on incorporating certified design information into a COL application and those requirements should be the starting point for COL application guidance. NEI stated that they would provide an example of information that was already approved in a design certification and an early site permit versus information that is part of the COL application.

With regard to site specific ITAAC, NEI stated that they do not regard this as being different as compared with ITAAC included in a design certification rule. The ITAAC would focus on key aspects of the design feature. NEI stated that applicants would only provide site-specific design ITAAC for significant interface requirements (see Attachment 7, Slide 8). The NRC staff objected to this statement, stating that ITAAC was not part of the basis for interface requirements and that they would expect ITAAC on site specific features such as the cooling tower and service water system.

NEI further commented on several specific topics as discussed below:

Reliability Assurance Program: NEI noted that this was new to design certification and that a draft SRP existed and it is assumed that it will be available. NEI also noted that the operational reliability assurance program was a combination of existing programs.

Quality Assurance (QA): NEI noted that the regulatory guides were outdated and the associated SRP section had been removed from use. While an example exists for an operating QA program, there is no example of a construction QA program. NEI requested that the staff update the guidance in this area. They also stated that they regard this issue as a high priority.

Technical Specifications (TS): With regard to making major changes to the generic TS from the certified design, NEI would like the staff to comment on their proposal to submit one exemption request covering changes in the TS that are not bracketed. In addition, NEI would like to know if this exemption request should be included with the COL application or after discussions with the NRC. NEI also stated that the applicants would identify TS that they regard as generic.

NEI noted that information for certain portions of the plant specific TS may not be available when the COL application is submitted to the NRC. In addition, certain TS supporting documents, such as the offsite dose calculation manual, will not be available at the time of the COL application. NEI would like the NRC comment on whether these issues would need to be resolved before the COL is issued or would conditions on the license be appropriate to address certain issues in this area.

Chapter 19 (Severe Accidents) and the Probabilistic Risk Assessment (PRA): NEI stated that they are considering streamlining Chapter 19 such that it will not include everything that was included in the design control document (DCD) of the certified design. NEI noted that they are proposing that the DCD be referenced in the safety analysis report and not an integral part of the report. The NRC staff noted that Chapter 19 of each DCD is different and stated that further discussions in this area would be necessary.

NEI also noted that the COL action items in design certifications (such as the AP1000) discuss as-built information. The NRC stated that there was no correlation between the COL action items and the proposed rule changes to 10 CFR Part 52.

NEI stated that they envision PRA as a separate document from the safety analysis report that would be retained from the design certification as opposed to be resubmitted. The NRC staff stated that, in light of the recent notice of proposed rulemaking for 10 CFR Part 52, that additional discussions on this issue were necessary.

Human Factors Engineering: NEI briefly noted issues in this area for future discussion including which ITAAC should be completed for the COL application and the time table at which human factors engineering issues should be resolved (prior to COL, at COL and after COL). NEI stated that they believe the following issues can be resolved after the COL is issued: 1) human system interface design, 2) human factors validation and verification, and 3) design implementation.

NRC COL Review Guidance: NEI requested that the staff provide them with a status of the SRP update. Their belief is that a COL review standard would be helpful as it was in the review of ESPs. NEI stated that if they had a choice, they would ask the NRC to develop a COL review standard before completing the SRP update, but not at the expense of the review of NEI 04-01. NEI further stated that a COL review standard would be a complement to the application guidance and committed to look at what they can do to provide a bridge to a NRC COL review standard. The NRC stated that it had limited resources available but would like to discuss the issue further and identify specific areas where the NRC could possibly provide review guidance.

Concluding Remarks

NEI concluded the meeting by stating that their first priority was to complete the COL application guidance document and submit it to the NRC sometime in December 2004. In addition, they requested discussions with the NRC on operational programs, Chapter 19/PRA, criteria for site specific design ITAAC, a COL review standard, and plant-specific TS. The NRC stated that meetings on operational programs could take place sometime in January 2005. NEI proposed that the inservice testing and inservice inspection operational programs be the subject of those meetings.

/RA/

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Office of Nuclear Reactor Regulation

Project No. 689

Attachments: 1. List of attendees and agenda

cc w/ atts: See next page

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ADAMS ACCESSION NUMBER:ML043240352 * see previous concurrence

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DATE	12/16/04	11/29/04	12/3/04	12/15/04

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EP ITAAC and Issues Associated With a Combined License (COL) Application
NEI Meeting
November 9, 2004
Attendance List

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Laura Dudes	NRR/DRIP/RNRP
Joe Colaccino	NRR/DRIP/RNRP
Steven Bloom	NRR/DRIP/RNRP
Jerry Wilson	NRR/DRIP/RNRP
Dariusz Szwarc	NRR/DRIP/RNRP
Dan Barss	NSIR/DPR/EPD
Bruce Musico	NSIR/DPR/EPD
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Bob Weisman	OGC
Marty Stutzke	NRR/DSSA/SPSB
Darrell Roberts	NSIR/DPR/EPD-A
Steve Tingen	NRR/DIPM/IPSB
Naeem Iqbal	NRR/DSSA/SPLB
Patrick Sekerak	NRR/DE/EMEB
Don Johnson	NSIR
David Terao	NRR/DE/EMEB
Thomas Kenyon	NRR/DRIP/RLEB
Carl Schulten	NRR/DIPM/IROB

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Kenneth Weirman
James Purvis

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Adrian Heymer
Russell Bell
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Bob Fuld

Other Interested Attendees

Al Passwater	Polestar
J. G. Cesare	Enercon Services
J. Alan Beard	GE Nuclear
Eddie Grant	Exelon
Michael Bourgeois	Entergy
Steve Routh	Bechtel
Michael Soslard	AECL
Jim Chapman	Scientech
Steve Frantz	Morgan Lewis
Shinichi Hayatune	Energy USA
Hiroyki Yoshida	Toshiba
Sandra Sloan	Areva
Carl Berger	Energetics
Yuichi Hayashi	AP1000 Project Westinghouse (Kansai)
Don Hutchings	Westinghouse
Jim Winters	Westinghouse
Geroge Zinke	Entergy
Joe Hegner	Dominion
Charles Brinkman	Westinghouse
Larry Dibal	Black & Veatch
John Costello	Dominion
Ben George	Southern Nuclear

Agenda

November 9, 2004, Meeting with Nuclear Energy Institute (NEI) Regarding Emergency Planning, Inspections, Tests, Analyses, and Acceptance Criteria (EP ITAAC), and Issues Associated with a Combined License (COL) Application

Time	Subject	Presenter
1:00 pm	Introductions and opening remarks	NRC/NEI
1:05 pm	Emergency Preparedness Inspection, Test, Analysis, and Acceptance Criteria (ITAAC)	NRC
2:00 pm	Discussion of Staff Requirements Memorandum to SECY 04-0032 - Programmatic Information Needed for Approval of A Combined License Without ITAAC	NRC
2:15 pm	Overview of Plans and Scope of NEI 04-01, Guidelines for Combined License (COL) Applications	NEI
2:30 pm	Break	
2:45 pm	Discussion of Specific COL Application Issues	NEI

- COL Application Contents, Including Final Safety Evaluation Report (FSAR)
- Scope and Level of Detail of Plant-Specific Design Description and ITAAC
- Operational Reliability Assurance Program and COL Design Reliability Assurance Program
- FSAR Chapter 19 (Severe Accidents) and the Probabilistic Risk Assessment
- FSAR Chapter 18 (Human Factors Engineering)
- COL Application Treatment of Operational Programs
- Development of Plant-Specific Technical Specifications
- NRC Staff Review Guidance for COL Application

4:45 pm	Public comment	
5:00 pm	Adjourn	

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